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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/538,809	12/23/2005	Christophe Mathoulin	062845-5052 US	5678

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MORGAN, LEWIS & BOCKIUS LLP
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EXAMINER

WOODALL, NICHOLAS W

ART UNIT	PAPER NUMBER
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3733

MAIL DATE	DELIVERY MODE
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06/04/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/538,809	Applicant(s) MATHOULIN ET AL.	
	Examiner Nicholas Woodall	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 June 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>04/04/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This action is in response to applicant's amendment received on 04/04/2007.

Allowable Subject Matter

2. The indicated allowability of claims 9 and 12 is withdrawn in view of the newly discovered reference(s) to McGuire. Rejections based on the newly cited reference(s) follow.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

4. Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Regarding claim 4, the claim reads, ...and a hollow spherical cap. The examiner is unclear to the limitation the applicant is trying to present in the claim. For examination purposes the examiner will interpret the claim wherein the recess is in the form of a hollow spherical cap.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1-6, 19, and 20 are rejected under 35 U.S.C. 102(e) as being anticipated by Huebner (U.S. Publication 2004/0127901).

Regarding claim 1, Huebner discloses a device comprising lateral holes and a flat face capable of being in contact with the bones being treated (reference Figure 1 below). The holes are at an angle to direct the screws towards the outside edge of the plate. Huebner shows various embodiments of the device, one including a flat face that contacts the surface of the bone (see Figure 2 and Figure 3 below). Regarding claim 2, Huebner further discloses a device that is circular in shape. Regarding claims 3 and 4, Huebner further discloses a device wherein the upper face comprises a recess (claim 3). The recess occupies a majority of the upper face of the device and is the form of a hollow spherical cap (claim 4; page 4 paragraph 37). Regarding claim 5, Huebner further discloses a device further comprising at least one screw hole in the form of a hollow spherical section and a screw with a matching head to allow a multidirectional orientation of the screw (see Figure 4 below). Regarding claim 6, Huebner discloses the device further comprising a number of holes close to the number of bone being treated. In one embodiment, Huebner shows a device comprising four holes to allow screws to pass into four different bones. Regarding claim 19, Huebner discloses a device wherein the plate comprises a number of screw holes equal to the number of bones to be treated. Regarding claim 20, Huebner discloses an embodiment wherein the device is connected to four carpal bones with four screws going through the four holes as shown in Figure 1 below (page 3 paragraph 28).

Figure 1

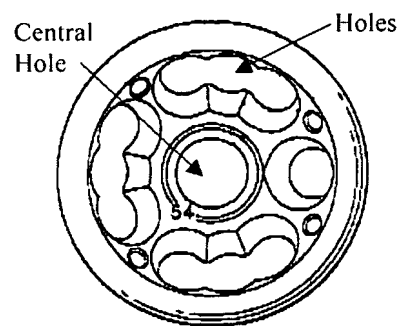


Figure 2

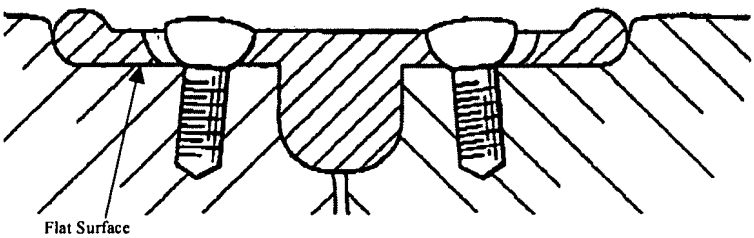


Figure 3

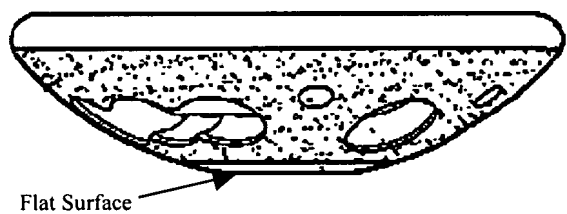
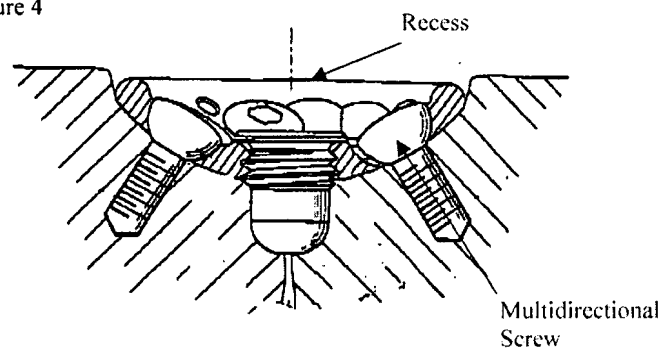


Figure 4



Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Huebner (U.S. Publication 2004/0127901) in view of Huebner (U.S. Publication 2004/0102778).

Regarding claim 7, Huebner discloses a device further comprising a central hole that is capable of allowing a sliding engagement between the device and a spindle. Huebner fails to disclose the device comprising markings on the periphery of the device. Huebner teaches a similar device comprising reference marks in order to indicate an angular or linear disposition (page 5 paragraphs 67 and 68 and page 6 paragraphs 68 and 69). It would have been obvious to one having ordinary skill in the art at the time the invention was made to manufacture the device of Huebner with reference markings in view of Huebner in order to indicate an angular or linear disposition.

10. Claims 8 and 13-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huebner (U.S. Publication 2004/0127901) in view of Huebner (U.S. Publication 2004/0102778) further in view of Weiss (U.S. Patent 6,179,839).

Regarding claims 8 and 13-18, the combination of Huebner and Huebner disclose the invention as claimed except for a set of instruments comprising a reamer. Weiss teaches a device further comprising a set of instruments including a reamer in order to rasp or burr away bone in a precise location where the device is to be

positioned and affixed (column 5 lines 36-55). It would have been obvious to one having ordinary skill in the art at the time of the invention to manufacture the device of Huebner as modified by Huebner with a set of instruments including a reamer in view of Weiss in order to rasp or burr away bone in a precise location where the device is to be positioned and affixed.

11. Claims 9 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huebner (U.S. Publication 2004/0127901) in view of Huebner (U.S. Publication 2004/0102778) further in view of Weiss (U.S. Patent 6,179,839) further in view of McGuire (U.S. Patent 5,374,270).

Regarding claims 9 and 12, the combination of Huebner, Huebner, and Weiss disclose the invention as claimed except for the reamer including a cannula and the device further comprising a spindle. Weiss teaches a device wherein the reamer further includes a cannula and further comprising a spindle, wherein the spindle is capable of being placed through the cannula of the reamer in order to insert the spindle into tissue for fixing material to the bone (column 2 lines 60-62). It would have been obvious to one having ordinary skill in the art at the time the invention was made to manufacture the device of Huebner modified by Huebner further modified by Weiss wherein the reamer includes a cannula and the device further comprises a spindle in view of McGuire in order to insert the spindle into tissue for fixing material to the bone.

12. Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huebner (U.S. Publication 2004/0127901) in view of Huebner (U.S. Publication

2004/0102778) further in view of Weiss (U.S. Patent 6,179,839) further in view of Griner (U.S. Publication 2004/0039450).

Regarding claims 10 and 11, the combination of Huebner, Huebner, and Weiss discloses the invention as claimed except for providing a provisional implant identical to the actual implant. Griner teaches using provisional implants that are identical to the actual implant in order to test the fit and alignment with a bone that has been reshaped by a surgeon without the possibility of damaging the actual implant (page 1 paragraph 002). It would have been obvious to one with ordinary skill in the art at the time the invention was made to manufacture the device of Huebner modified by Huebner further modified by Weiss with an identical provisional implant in view of Griner in order to test the fit and alignment with a bone that has been reshaped by a surgeon without the possibility of damaging the actual implant.

Response to Arguments

13. Applicant's arguments filed 04/04/2007 have been fully considered but they are not persuasive. The examiner has presented a new ground of rejection for claims 9 and 12, which were previously indicated as allowable. This office action is non-final, since the examiner has withdrawn previously indicated allowability of claims 9 and 12.

Regarding applicant's argument that Huebner does not disclose each limitation of claim 1 is not persuasive. The examiner has included additional figures from Huebner showing discussed embodiments that clearly shows the face of the device contacting the bone is flat (reference Figure 2 and Figure 3 above).

Regarding applicant's argument concerning claim 7 that the examiner did not provide a sufficient *prima facie* case of obviousness is not persuasive. Regarding claim 7, the examiner stated that the first Huebner reference discloses the invention as claimed through claims 1-6 and further including a central hole capable of being positioned on a spindle as discussed above. The examiner then states that the first Huebner reference fails to disclose the device further comprising markings situated at the periphery of the device. The examiner then states that the second Huebner reference teaches a device that comprises markings situated at the periphery of the device with the motivation to indicate an angular or linear disposition. Therefore, the examiner has presented a sufficient *prima facie* of obviousness regarding claim 7.

Regarding applicant's argument concerning claims 8 and 13-18 that the examiner did not provide a sufficient *prima facie* case of obviousness is not persuasive. Regarding claims 8 and 13-18, the examiner stated that the combination of the first Huebner reference and the second Huebner reference disclosed the invention as claimed through claims 1-7 as discussed above. The examiner then states that the combination of the first Huebner reference and the second Huebner reference fail to disclose the device further comprising a set of instruments including a reamer. The examiner then states that the Weiss reference teaches a similar device that comprises a set of instruments including a reamer with the motivation to rasp or burr away bone in a precise location where the device is to be positioned and affixed. Therefore, the examiner has presented a sufficient *prima facie* of obviousness regarding claims 8 and 13-18.

Regarding applicant's argument concerning claims 10 and 11 that the examiner did not provide a sufficient *prima facie* case of obviousness is not persuasive.

Regarding claims 10 and 11, the examiner stated that the combination of the first Huebner reference and the second Huebner reference and the Weiss reference disclosed the invention as claimed through claims 1-8 as discussed above. The examiner then states that the combination of the first Huebner reference and the second Huebner reference and the Weiss reference fail to disclose the device further comprising an identical provisional implant, i.e. dummy plate. The examiner then states that the Griner reference teaches a similar device that comprises an identical provisional implant with the motivation to test the fit and alignment with a bone that has been reshaped by a surgeon without the possibility of damaging the actual implant. Therefore, the examiner has presented a sufficient *prima facie* of obviousness regarding claims 10 and 11.

Conclusion

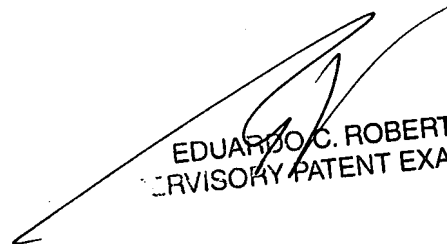
14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892 for cited references the examiner felt were relevant to the application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicholas Woodall whose telephone number is 571-272-5204. The examiner can normally be reached on Monday to Friday 8:00 to 5:30 EST..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NWWW



EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER